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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,072	03/12/2004	Martin John Glenton Hughes	GJE-70D1	9134

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,072	HUGHES ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 18-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/04 and 8/9/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response to the restriction filed 9/26/06 has been entered into the record.

Election/status of claims

2. Applicant's election Group VI claims 13-17 with respect to pho2-15, SEQ ID NO: 13 drawn to a method for prevention or treatment of a condition associated with bacterial infection 9/26/06 is acknowledged. Since no arguments put forth to support traversal, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a).

Claims 13-17 with respect to pho2-15, SEQ ID NO: 13 are under examination. Applicant is advised to amend the claims to the elected invention pho2-15, SEQ ID NO: 13

Claims 1-12 and 18-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

3. Information Disclosure Statements filed on 6/7/04 and 8/9/06 are acknowledged and a signed copy of each is attached to this Office action.

Claim Rejections - 35 U.S. C. § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 13-17 are rejected under 35 U.5.C. 112, first paragraph, as containing subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published June 15, 1998 in the Federal Register at Volume 63, Number 114, pp 32639-32645 (also available at www.uspto.gov). This is a written description rejection.

The specification only teaches that the present invention is based on the identif icatlon of a series of genes in GSS, and also related organism , the products of which **may** be localised on the outer surface of the organism and therefore **may** be used as a target for Immuno-therapy. The specification only comtemplates that "Homologues to the GBS pho2-l5 gene product can be identified in Streptococcus pyogenes, Streptococcus pneumoniae. Enterococcus faecalis and E. coli (gatc and Sgcc). The S. pyogenes, S. pneumoniae and E. faecalis homologues were identified from gene seguence data and no annotations were available as to the identity of the gene or gene products. In E. coli, (gatC and SgcC) gene products can be identified as being the IIC component of phosphoenolryruvate-dependent sugar phosphotransferase systems (PTS), a major carbohydrate active-transport system. In PTS systems, the component is typically involved in binding of extracellular carbohydrates and forms a complex with the IID component to constitute a membrane channel (Nobelmann, B. and J.W. Lengeler. 1995. Biochem. Biophys. Acta 1262:69-72). However, the specification fails to teach the function or localization of peptide, SEQ ID NO:13 and homologue or a functional fragment of said sequence.

Claims are drawn to a method for the treatment or prevention of a condition associated with bacterial infection, wherein said method comprises administering to a patient in need of such treatment or prevention, an effective amount of a peptide encoded by a polynucleotide sequence wherein said polynucleotide sequence comprises a gene, obtainable from a

Group B Streptococcus pho 2-15 or said polynucleotide sequence comprises a homologue or a functional fragment of one of said Group B Streptococcus genes, wherein said peptide comprises an amino acid sequence 13 , wherein the infection is a Group B Streptococcal infection , wherein the infection is a local infection, wherein the infection is a urinary tract infection.

The instant specification may provide an adequate written description for a polynucleotide sequence encoding the GBS (Group B Streptococcus) M732 polypeptide as set forth as SEQ.ID.NO:13 . However the specification fails to disclose polynucleotide sequence encoding a homologue or a functional fragment of said polypeptide SEQ.ID.NO:13 (the examiner is going to refer homologue or functional fragment as variants/fragments here after in the action) .

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity

of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims drawn to a method of treating or preventing conditions associated with bacterial infection using either polynucleotide encoding the polypeptide SEQ.ID.NO:13 or homologue or fragments of said polypeptide such as those at issue here. The specification fails to teach a single fragment or homolog of a polypeptide sequence of SEQ ID

NO: 13 . The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotides encoding a representative number variants/fragments of SEQ ID NO: 13, as per Lilly by structurally describing a representative number of variants/fragments or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus" have to disclosed. In this application such structural features common to the claimed variants/fragments have not been disclosed. Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." In this case, the specification does not disclose nucleic acid molecule encoding variants/fragments of polypeptide SEQ.ID.NO:13, required to practice the claims 13-17 in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any variants/fragments nor does the specification provide any partial structure of such variants/fragments, nor any physical or chemical characteristics of the variants/fragments nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses an isolated nucleic acid encoding the recombinant protein comprising the amino acid sequence SEQ.ID.NO:13. and does not provide a description of variants/fragments of said polypeptide that would satisfy the standard set out in Enzo.

The specification also fails to describe the variants/fragments by the test set out in Lilly. Therefore, it necessarily fails to describe a "representative number" of such species, variants/fragments using all bacterial infections. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a

substantial portion of the genus." Thus, the specification does not provide an adequate written description for a method for the treatment or prevention of a condition associated with bacterial infection, wherein said method comprises administering to a patient in need of such treatment or prevention, an effective amount of a peptide encoded by a polynucleotide sequence wherein said polynucleotide sequence comprises a gene, obtainable from a Group B Streptococcus pho 2-15 or said polynucleotide sequence comprises a homologue or a functional fragment of one of said Group B Streptococcus genes, wherein the infection is a local infection, wherein the infection is a urinary tract infection that is required to practice the claimed invention.

Claims do not comply with 35 USC 112, first paragraph because it is not supported by an adequate written description in the specification for the claimed method using a peptide homolog/fragment of SEQ.ID.NO:13.

6. Claims 13-17 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims have been discussed supra.

This is a full enablement rejection for the claimed method.

While the disclosure provides guidance how to make the claimed polypeptide SEQ ID NO: 13 encoded by the nucleic acid and how to treat infection caused by *S. agalactiae* , the specification fails to disclose SEQ.ID.NO:13 or variants/fragments of SEQ ID NO: 13 to treat or prevent bacterial infections. Therefore, the use of SEQ.ID.NO:13 or variants/fragments in a method for treating t or preventing bacterial infections are not yet known or taught by the disclosure.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The teaching of the specification cannot be extrapolated to enable the scope of the claims because the claims as broadly drawn include treating or preventing bacterial infections using variant/fragment of protein SEQ.ID.NO: 13. However, using such variants/fragments thereof is sufficient for treating broadly claimed bacterial infections is acknowledged to be unpredictable because the specification fails to disclose the critical residues that are important or any changes made in a polypeptide SEQ.ID.NO: 13 encoded by nucleic acid sequence to obtain variant/fragment that can be used to treat or prevent infection caused by gram negative and gram positive bacteria. The specification provides no information on the immunogenicity of protein variants/fragments encoded by the nucleic acid, the claimed fragments, the variants or the ability of such to protect from bacterial infections. The

specification fails to teach that the claimed nucleic acids encoding the polypeptide or fragments are capable of generating a humoral or cellular immune response such that broadly claimed gram positive and negative bacterial infections can be treated or prevented. The specification also fails to teach that the immune response to the polypeptide encoded by the nucleic acid, alone or in combination with adjuvants or carriers provides for a protection against bacterial infection in any acceptable animal model. The specification fails to teach any immune response generated by means of a nucleic acid encoding variants/fragments. It is well recognized in the art, that it is unclear whether an antigen(s) derived from a pathogen will elicit protective immunity. Ellis, R.W. (Chapter 29 of "VACCINES" [Plotkin, 5.A. et al. (eds) published by W. B. Saunders company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.... and thus protect the host against attack by the pathogen". The specification fails to teach even one of the claimed polynucleotide encoding polypeptides or fragments thereof alone or in combination with other antigens does in fact confer protection from infection, as is requisite of a method of treatment or prevention. In the absence of a teaching of the claimed polynucleotide encoding the peptide as set forth in SEQ.ID.NO: 13 can generate an immune response and that immune response is effective in prevention or treatment of any and all bacterial infections, the specification is not be enabled for a method of treatment or prevention of any and all bacterial infections with the claimed fragments/variants/ homologs of peptide as set forth in SEQ.ID.NO: 13. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

The specification provides no working examples demonstrating (i.e., guidance) enablement for using the peptide SEQ.ID.NO:13 or variant/fragment/homolog of said peptide in treating bacterial infections . Since the specification does not teach how to make variants/fragments of SEQ.ID.NO: 13, the skilled artisan would not be able to use the claimed variant/fragment in a method for treating or preventing bacterial infections. In addition the specification does not disclose that the isolated polypeptide SEQ.ID.NO:13 is able to treat bacterial infections when administered. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

If applicants were able to overcome the rejection as set forth above, the claims still would be rejected under scope of enablement , while enabling for a method of treatment of Group B streptococcal infections , wherein said method comprises administering to a patient in need of such treatment an effective amount of a polypeptide encoded by a polynucleotide sequence comprising the amino acid sequence SEQ.ID.NO:13 obtained from a Group B Streptococcus pho 2-15 , wherein the infection is a local infection or a urinary tract infection, does not reasonably enabled for a method for the treatment or prevention of a condition associated with bacterial infection, wherein said method comprises administering to a patient in need of such treatment or prevention, an effective amount of a peptide encoded by a polynucleotide sequence wherein said polynucleotide sequence comprises a gene, obtainable from a Group B Streptococcus pho 2-15 or said polynucleotide sequence comprises variants/fragments one of said Group B Streptococcus genes, wherein the infection is a Group B Streptococcal infection , wherein the infection is a local infection, wherein the infection is a urinary tract infection.

Claim Rejections-35 U.5.C. 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 13-17 are rejected under 35 U.5.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite in the recitation of pho2-15. The relative term in claims renders the claim indefinite. The recitation of the pho2-15 appears to be lab designation. Since this is merely a lab designation, such designation change from lab to lab or the same designation can be used for totally different genes, recitation of pho2-15 must be designated or identified by Sequence identification number or ATCC number.

Claim 13 is rejected as being vague because the claim is drawn to a method for treatment or prevention of a condition associated with bacterial infection. In general prevention means prophylactic. Therefore, recitation of "a method for the treatment of a disease associated with bacterial infection ---- or a method for the prevention of bacterial infection ---" is appropriate. Further it is not clear what applicant means by condition associated with bacerial infection?

Claims 13-17 are indefinite as depending upon non-elected subject matter and applicant is advised to amend the claims to restrict to SEQ.ID.NO: 13.

Status of Claims

9. No claims are allowed.

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Bruce Campell can be reached on (571) 272-0. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

MARK NAVARRO
PRIMARY EXAMINER